

## "How to Operate Within the Law: Patents on Medical Procedures"

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### Should Congress Get Involved in Looming Ethical Issues?

What do medical ethics have in common with the patent system? Not much, it seems, given a recent controversy concerning the propriety of doctors obtaining patents on surgical and other medical techniques.

Tension between the patent system and other fields of human endeavor is not new, of course. It is true that nearly everyone seems to be in favor of the patent system, so that innovation is encouraged and inventors are rewarded for their intellectual labor.

On occasion, however, patent law's reach into certain areas causes discomfort, when the values fostered by the patent system seem to clash with other values.

One such area of controversy concerns no less than the realm of life itself. Under patent law, an inventor is entitled to legal protection, in the form of a patent, for certain useful, new and non-obvious inventions. But what is an "invention?" Does it include the creation of new forms of life?

In America at least, this question was settled in the affirmative just a few years ago. Although human organisms are not patentable, animal life now is.

For example, in the late 1980s, Harvard University received the first patent on animal life — the oncomouse or "Harvard mouse." Many object to such patents, on the grounds that it is the ultimate in hubris to believe that man can truly invent or own a form of life.

### Hippocrates and Innovation

Another controversy concerns the granting of patents on medical techniques, such as new surgical procedures. Should a doctor be able to obtain a legal monopoly over the practice of a new surgical technique? Should he or she be financially rewarded for such useful medical innovations, or should all other doctors and patients have an automatic right to use these ideas for free?

Many countries do not allow patents to be granted on medical techniques. One reason for this policy is that there is a perceived conflict between the rights accorded a patentee and ethical obligations of a physician. The U.S. Patent and Trademark Office (PTO), however, has been issuing medical procedure patents for decades.

The recent controversy rose to a head as a result of a notorious lawsuit, *Pallin v. Singer* (36 U.S.P.Q.2d 1050 (1995)). In this case, an eye surgeon who had obtained a patent for a special cataract surgical technique sued other doctors for infringement of his patent. The defendants ultimately prevailed, however, when the court entered a consent order, effectively decreeing the patent invalid.

Thus, although medical procedure patents are obtainable in the U.S., there did not seem to be a significant conflict in actual practice between patentees and doctors. In short, it did not look like patentees would be very likely to abuse such patents.

In the wake of the *Pallin* case, however, many groups, such as the American Medical Association, condemned the patenting of medical and surgical procedures, and began to lobby Congress to exempt such procedures from patent protection.

The American Academy of Ophthalmology (ACO) argued, for example, that such patents cause monopoly prices to be charged for health care, helping to increase health care costs. Also, because of the danger that some doctors will keep their medical innovations secret in hopes of obtaining a patent, the ACO warned that the lure of medical patents may induce physicians to shirk their obligation to share their knowledge and skills for the benefit of humanity.

Pro-inventor groups, however, strongly opposed changing the patent law, fearing that fewer medical innovations would be forthcoming if the encouragements of the patent system were removed. In addition, the inventor groups also cautioned that exempting medical procedures from patent protection would unfairly discriminate between different types or classes of inventors and inventions.

Further, since the *Pallin* case was, after all, resolved in favor of the alleged patent infringers, any reaction by Congress might be an overreaction. Advocates of the patent system also feared that such a change in the law would proclaim an "open season" for exceptions to patent protection.

Not all opponents of medical procedure patents advocated entirely exempting medical procedure patents from patent protection. Instead, they proposed different, arguably less radical, alternative approaches.

For example, one solution would be to simply shorten the term of medical procedure patents (patents currently last 20 years from the date of filing). Others suggested allowing medical procedure patents only for medical techniques that also require FDA approval.

Another proposed solution would be to institute a system of "prior user" rights, which allows doctors already secretly using a later-patented technique to continue using it.

Still others have proposed compulsory licensing, which is not generally available under U.S. law. Under the U.S. system, a patentee can refuse to license his patent to others, effectively preventing anyone else from practicing the patented invention, for any price.

Under a compulsory licensing scheme, owners of certain key medical patents would be forced to license their patented techniques for a reasonable royalty. Although this would still arguably increase the costs associated with certain techniques, important patented medical procedures could not be withheld from the market.

### **Congress Steps In**

Congress ultimately adopted a compromise solution, which was buried in the 1997 Omnibus Consolidated Appropriations Act. This law added a new

Subsection 287(c) to the patent statute (Title 35, U.S.C.), which provides that the standard patent remedies are not available against a “medical practitioner” or “related health care entity” with respect to the medical practitioner’s performance of a medical activity that infringes a patent.

In other words, the new provision denies patentees the standard remedies for patent infringement by a medical practitioner’s performance of a medical activity, with certain exceptions.

Thus, under the new law, even if a doctor performs a patented medical procedure, and thus technically infringes the patent, the patent owner is unable to pursue any remedies (e.g., injunction or damages) against the doctor, or other medical practitioner or related health care entity (such as nurses, hospitals, and the like).

However, as some commentators have pointed out, the new law only limits the remedies that the patent owner can pursue against certain infringers; the law does not prohibit the obtaining of medical procedure patents, and even contemplates their technical “infringement.”

A company that manufactures medical devices, pharmaceuticals, etc., may still be held liable for active inducement or contributory patent infringement.

For example, suppose a medical device company manufactures a special device designed to be used to perform a patented technique. If the company sells the device to a doctor who then uses it in performing the patented surgery, the doctor is a “direct” infringer of the patent, although he and his hospital may bear no liability due to the new amendments.

However, in these circumstances, the medical device company may be held liable for contributory infringement, because the company sold the special device to the doctor.

As for inducement, U.S. patent law provides that “whoever actively induces infringement of a patent shall be liable as an infringer.” Thus, in addition to the danger of contributory infringement, if a company actively induces a doctor to infringe a medical procedure patent, the company may be liable for inducing infringement, if the company itself is not exempt from liability under the new subsection.

For example, a hospital or medical center that provides a seminar to doctors which teaches how to perform a patented technique may be in danger of inducing infringement, even though the doctors themselves may bear no liability for their acts of direct infringement.

Medical device and related companies should not be lulled into a false sense of security by the hype surrounding the new law. Whenever a possibly relevant medical patent comes to the attention of these companies, as well as doctors, they should carefully examine the new patent amendments, to ensure that they are operating within the law.

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